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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,708	06/12/2001	Se-Jin Lee	JHUI320-4	7387

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EXAMINER

ROMEO, DAVID S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	Application No. 09/880,708	Applicant(s) LEE ET AL.	
	Examiner David S Romeo	Art Unit 1647	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 17 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

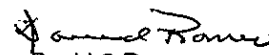
Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 2-8, 11 and 12.

Claim(s) withdrawn from consideration: 9, 10, 13 and 14.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
David S Romeo  
Primary Examiner  
Art Unit: 1647

Continuation of 2. NOTE: The proposed amendment would require further consideration and/or search of "altered expression," "in a subject in need thereof," and "normal expression" and raises new issues under 35 USC § 112.

Continuation of 5. does NOT place the application in condition for allowance because: Claim Rejections - 35 USC § 112: Claims 2-8, 11, 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting GDF-5 comprising the amino acid sequence shown in figure 2, does not reasonably provide enablement for a method of detecting a cell proliferative disorder by detecting GDF5.

Applicant maintains the traversal of this ground of rejection for reasons of record and amends the claim. Applicant's arguments have been fully considered but they are not persuasive for reasons of record and because Applicant's arguments are directed to the newly proposed or amended claims and that amendment has not been entered.

Claims 2-8, 11, 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2-8, 11, 12 are indefinite because they recite the term "GDF5".

Applicant's arguments have been fully considered but they are not persuasive. Although the antibody binds a GDF-5 having an amino acid sequence as set forth in SEQ ID NO: 10 or SEQ ID NO: 13, the claims do not require that the "GDF" that is detected by the claimed method have an amino acid sequence as set forth in SEQ ID NO: 10 or SEQ ID NO: 13. Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "GDF5" an artisan cannot determine what additional or material limitations are placed upon a claim by the presence of this element. The metes and bounds are not clearly set forth. Applicant's arguments are directed to the newly proposed or amended claims and that amendment has not been entered.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 is indefinite because it recites the term "modified cellulose." Applicant argues that a skilled artisan would know the modifications intended by the term "modified." Applicant's arguments have been fully considered but they are not persuasive. The language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement. Applicant's arguments are directed to the newly proposed or amended claims and that amendment has not been entered.

Claims 2-8, 11, 12, 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2-8, 11, 12, 14 are indefinite because they recite the term "normal cell." Applicant's arguments are directed to the newly proposed or amended claims and that amendment has not been entered.